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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,166

07/23/2003

Gregory Everett Amidon

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09/04/2009

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

09/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSNY@Pfizer.com

Office Action Summary	Application No. 10/626,166	Applicant(s) AMIDON ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/03/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/26/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/03/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,8-9,13-20 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Holman (US 6,277,875 B1, cited by applicants), for the reasons set forth in the previous office action filed 06/06/2008 and 01/29/2009.

Claims 1-4,8-4,19-20,22,24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. (US 2003/0180352), for the reasons set forth in the previous office action filed 06/06/2008 and 01/29/2009.

Applicant's arguments filed 08/03/2009 have been fully considered but they are not persuasive.

Applicants assert that Holman describes immediate release formulations of Mirapex which is also described within applicant's specification as immediate release.

The relevance of this assertion is unclear. Holman teaches the tablets can contain an enteric coating which controls the location in the digestive system where the formulation is released. Since the coating prevents release of the active before it reaches the intestines the examiner does not consider at least in every embodiment of Holman as only being drawn to immediate release. Furthermore it is noted by the examiner that applicants have not set forth in their claims any differences in the composition of their claims and the tablets of Holman, thus since the scope of applicants claimed invention and Holman overlap it is inherent that the formulations will have the same release profile.

Applicants assert that Patel's first stated object is to provide active ingredients in a rapidly dissolvable state.

The relevance of this assertion is unclear. What applicants refer to above is just one embodiment of many within the Patel reference. Furthermore clearly Patel teaches that the dosage forms can provide a sustained therapeutic effect. See [0045] and [0046].

Applicants further assert that their claimed invention would not be clear to one of ordinary skill in the art from the description within Patel because it would require combining elements from among tens of thousands of possible combinations.

The examiner respectfully disagrees. First it is noted by the examiner that pharmaceutical compositions in general is a very old and mature field and it is well known that numerous types of actives, binders and other excipients can be combined in almost any conceivable way and one of ordinary skill in the art could readily envision any combination of various ingredients as long as they were described as being capable of being of use together. Clearly Patel teaches pharmaceuticals containing active ingredients including anti-Parkinson's drugs such as pramipexole and its salts, solubilizers such as HPMC and binders such as pregelatinized starch. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed"... *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1) alone or alternatively in view of Michaud et al. (EP 0,933,079 A1, cited previously), for the reasons set forth in the previous office action filed 06/06/2008 and 01/29/2009.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2003/0180352) alone or alternatively in view of in view of Michaud et al.

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(EP 0,933,079 A1, cited previously), for the reasons set forth in the previous office action filed 06/06/2008 and 01/29/2009.

Applicant's arguments filed 08/03/2009 have been fully considered but they are not persuasive.

Applicants assert that Michaud is drawn to immediate release formulations thus there would be no reasonable expectation of success nor motivation to arrive at applicant's claimed sustained release formulation. Applicants also assert that since Michaud discloses that the starch dissolves at a very high speed, the reference teaches away from applicants claimed sustained release formulation.

The examiner respectfully disagrees with the above assertions by applicants. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Michaud was only used for its description of the tensile strength of various starches and as a secondary reference it does not have to disclose all of applicants claimed invention. The primary references disclose sustained release formulations and as noted previously, one of ordinary skill in the art would have been motivated to combine the Michaud with Homan and Patel in order to achieve the disclosed advantages of the starches described in Michaud which produced hard tablets at low compression rates, a feature that would obviously be advantageous in industrial production and processability of a tablet.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618